Reference number(s)
1704-A

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab)
RUXIENCE (rituximab-pvvr)
TRUXIMA (rituximab-abbs)

Treatment of Rheumatoid Arthritis and Other Conditions

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Rituxan, Ruxience, and Truxima are indicated for:
1. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.
2. Non-Hodgkin's lymphoma (NHL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Oncology SGM)
3. Chronic lymphocytic leukemia (CLL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Oncology SGM)

Rituxan and Truxima are also indicated for:
Rheumatoid Arthritis (RA)
Rituxan or Truxima, in combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Rituxan is also indicated for:
Pemphigus Vulgaris (PV)
Rituxan is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris.

B. Compendial Uses
1. Sjögren's syndrome
2. Multiple sclerosis, relapsing remitting
3. Neuromyelitis optica (Devic disease)
4. Autoimmune blistering disease
5. Cryoglobulinemia
6. Solid organ transplant
7. Opsoclonus-myoclonus ataxia
8. Systemic lupus erythematosus
9. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Oncology SGM

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

A. Coverage will not be provided for requests for the treatment of rheumatoid arthritis (RA) when planned date of administration is less than 16 weeks since date of last dose received.
B. Member will not receive Rituxan, Ruxience, or Truxima with other biologics for RA.
C. Member will not receive Rituxan, Ruxience, or Truxima with other multiple sclerosis (MS) drugs excluding Ampyra

III. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for the treatment of moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX) unless the member has a contraindication (see V. Appendix) or intolerance to MTX and either of the following criteria are met:
   a. The member has previously received any biologic disease-modifying antirheumatic drug (DMARD) or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis; or
   b. The member has received at least two full doses of Rituxan, Ruxience, or Truxima for the treatment of RA, where the most recent dose was given within 6 months of the request.
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA in combination with MTX when either of the following criteria are met:
   a. The member has experienced an inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to 20 mg/week); or
   b. The member had an intolerable adverse effect or contraindication to MTX (see V. Appendix), and an inadequate response to another conventional DMARD (e.g., hydroxychloroquine, leflunomide, sulfasalazine).

B. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) and Churg-Strauss and pauciimune glomerulonephritis

Authorization of 12 months may be granted for treatment of GPA, MPA or and Churg-Strauss and pauciimune glomerulonephritis.

C. Sjögren's syndrome

Authorization of 12 months may be granted for treatment of Sjögren's syndrome when corticosteroids and other immunosuppressive agents were ineffective.

D. Multiple sclerosis

Authorization of 12 months may be granted for treatment of relapsing remitting multiple sclerosis (MS).

E. Neuromyelitis optica

Authorization of 12 months may be granted for treatment of neuromyelitis optica when at least one other immunotherapy was ineffective.

F. Autoimmune blistering disease

Authorization of 12 months may be granted for treatment of corticosteroid refractory autoimmune blistering disease (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus).

G. Cryoglobulinemia

Authorization of 12 months may be granted for treatment of cryoglobulinemia when corticosteroids and other immunosuppressive agents were ineffective.

H. Solid organ transplant

Authorization of 3 months may be granted for treatment of solid organ transplant and prevention of antibody mediated rejection in solid organ transplant.

I. Opsoclonus-myoclonus-ataxia
Authorization of 12 months may be granted for treatment of opsoclonus-myoclonus-ataxia associated with neuroblastoma when the member is refractory to steroids and chemotherapy.

J. Systemic Lupus Erythematosus
Authorization of 12 months may be granted for the treatment of systemic lupus erythematosus that is refractory to immunosuppressive therapy.

IV. CONTINUATION OF THERAPY

A. Rheumatoid arthritis
Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and achieve or maintain positive clinical response after at least two doses of therapy with Rituxan, Ruxience, or Truxima as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. Multiple Sclerosis
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for relapsing remitting multiple sclerosis (MS) who are experiencing disease stability or improvement while receiving Rituxan, Ruxience, or Truxima.

C. Other indications
Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and are receiving benefit from therapy.

V. APPENDIX

Examples of contraindications to methotrexate
A. Alcoholism, alcoholic liver disease or other chronic liver disease
B. Breastfeeding
C. Blood dyscrasias (e.g., bone marrow hypoplasia, thrombocytopenia, leukopenia, significant anemia)
D. Elevated liver transaminases
E. Hypersensitivity
F. Interstitial pneumonitis or clinically significant pulmonary fibrosis
G. Myelodysplasia
H. Pregnancy or planning pregnancy (male or female)
I. Renal impairment
J. Significant drug interaction

VI. REFERENCES

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